UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re Application of Betapharm Arzneimittel GmbH, Ratiopharm GmbH, and Zentiva Pharma GmbH for an Order Pursuant to 28 U.S.C. § 1782 Granting Leave to Obtain Discovery for Use in Foreign Proceedings	* * * * * * *	1:23-mc-91600-IT

MEMORANDUM & ORDER

February 5, 2024

TALWANI, D.J.

The Application for an Order Pursuant to 28 U.S.C. § 1782 to Conduct Discovery for Use in Foreign Proceedings ("Application") [Doc. No. 2] by Betapharm Arzneimettel GmbH ("Betapharm"), Ratiopharm GmbH ("Ratiopharm"), and Zentiva Pharm GmbH ("Zentiva") (collectively, "Petitioners") seeks leave to subpoena certain documents and records from various Massachusetts-based entities, including Millennium Pharmaceuticals, Inc. ("Millennium").[1] For the reasons that follow, the Application is DENIED.

I. Background

Millennium is a pharmaceutical company and, as relevant here, is the licensee of two European patents (the "EP'344 patent" and the "EP'667 patent"). Memorandum ISO Application 2 [Doc. No. 3]. Both patents are directed to a specific lyophilized compound or method of preparing a specific lyophilized compound, id., and were used by Millennium to formulate VELCADE, a drug for the treatment of multiple myeloma. Resp. Millennium's Opposition to Application ("Opposition") 1-2 [Doc. No. 31].

[1] The court previously granted as unopposed Petitioners' Application with respect to the Dana-Farber Cancer Institute, Inc., The Massachusetts General Hospital, The Brigham and Women's Hospital, Inc., and Beth Israel Deaconess Medical Center, Inc. See Elec. Order [Doc. No. 33].

A. *European Patent Office Invalidity Proceeding*

In 2019, several generic manufacturers, including Petitioners Betapharm and Zentiva, and Petitioner Ratiopharm's parent company, Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), challenged the validity of the EP'667 Patent in proceedings before the European Patent Office ("EPO") (the "2019 EPO invalidity proceeding"). Memorandum ISO Application 3 [Doc. No. 3]; Opposition 5 [Doc. No. 31]. In that proceeding, Teva Ltd. raised a prior public use argument, discussed in more detail infra Section I.C. Opposition 5 [Doc. No. 31].[2] In March 2022, the EPO rejected the Petitioners' arguments, including the prior public use argument. Decl. of Christopher James Hoggett ("Hoggett Decl.") ¶¶ 6-7 [Doc. No. 27]. The appeal of the EPO's decision is pending. Pets.' Sur-Reply ISO Application ("Sur-Reply") 3 [Doc. No. 47] (discussing EPO's issuance of provisional, non-binding opinion on appeal issued December 20, 2023).

B. *German Infringement Proceeding*

In 2022, Millennium brought an action against Petitioners in Dusseldorf District Court for infringement of both the EP '344 and the EP '667 Patents (the "German infringement proceeding"). Opposition 5 [Doc. No. 31]; Decl. of Dr. Ina vom Feld ("vom Feld Decl.") ¶¶ 2-3 [Doc. No. 28].[3]

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[2] Beginning in 2016, a separate subset of generic manufacturers challenged the EP '344 Patent in EPO proceedings. Opposition 4 [Doc. No. 31]. One of those manufacturers, Teva Pharmaceuticals, Inc. (which, like Ratiopharm, is a subsidiary of Teva Ltd.), sought to raise a prior public use challenge in its appeal of the EPO's decision. Id. The EPO refused to allow evidence of prior public use on appeal where the argument was not made in the initial proceedings. Id. Teva has petitioned for review of that decision on grounds unrelated to the public use challenge. Id. at 4 n.3.

[3] The parties agree that the German District Court hearing the German Infringement Proceeding does not have jurisdiction to address the validity of the patents. Memorandum ISO Application 3 (citing Decl. of Dr. Sebastian Hopfner ("Hopfner Decl.") ¶ 6 [Doc. No. 6]; Decl. of Dr. Sandra Lepthien ("Lepthien Decl.") ¶ 6 [Doc. No. 7]; Decl. of Jonathan J. Wurth ("Wurth Decl.") ¶ 6 [Doc. No. 5]) [Doc. No. 3]; Sur-Reply 1 (citing vom Feld Decl. ¶¶ 2-3 [Doc. No. 28]) [Doc. No. 47].

C. *German Nullity Proceedings*

In response to the infringement actions, each of the Petitioners brought a separate nullity proceeding before the German Federal Patent Court ("the German nullity proceedings") challenging the validity of the EP '344 Patent. Opposition 6 [Doc. No. 31].

As in the 2019 EPO invalidity proceeding, Petitioners are bringing a "prior public use" challenge to the patent's novelty. Id. Specifically, Petitioners allege that in conducting clinical trials in the early 2000s for VELCADE, "all the information about such trials, including the claimed lyophilized compound/powder [the drug] itself and the used vials and vial labels, was presumably disclosed to the patients and likely relatives, private doctors and clinical personnel not involved in the immediate conduct of the trials." Memorandum ISO Application 5 [Doc. No. 3].

A consolidated hearing in the nullity proceedings filed by Betapharm and Zentiva is scheduled for April 2024; Millenium anticipates that the German tribunal is likely to join the nullity proceeding filed by Ratiopharm to that consolidated hearing. Opposition 6 [Doc. No. 31].

D. *The Section 1782 Request*

In their Section 1782 request, Petitioners seek leave to serve subpoenas for documents from Millennium related to twenty-eight of the VELCADE clinical trials. Decl. of Jason H. Liss ("Liss Decl.") Ex. 1 [Doc. No. 25] (setting forth specific requests for Clinical Trial information); Decl. of Alice Choi ("Choi Decl.") ¶ 8 [Doc. No. 26] (clarifying the number of relevant clinical trials conducted by Millennium). Petitioners state that they seek to use this discovery in the 2019 EPO invalidity proceeding, the German infringement proceeding, and the German nullity proceedings. Memorandum ISO Application 6 [Doc. No. 3].

II. Standard of Review

A. Section 1782 Mandatory Requirements

28 U.S.C. § 1782 is a statutory mechanism to provide "federal-court assistance in gathering evidence for use in foreign tribunals." Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 247 (2004). Three requirements must be met in order for discovery to be proper under Section 1782: (1) the person from whom discovery is sought must "reside[] or [be] found" in the district where the petitioned court is located; (2) the request must seek the "testimony[,] statement…" "document or other thing for use in a proceeding in a foreign or international tribunal"; (3) the request must be made by an "interested person"; and (4) the requested material must not be protected by "any legally applicable privilege." 28 U.S.C. § 1782(a).

B. Intel Factors

If the mandatory Section 1782 requirements are met, the court exercises its discretion to allow or prohibit discovery based on the Intel four-factor test. "The first factor to consider is whether the person from whom discovery is sought is a party to the foreign proceeding, in which case 'the need for § 1782(a) aid generally is not as apparent' because a 'foreign tribunal has jurisdiction over those appearing before it, and can itself order them to produce evidence.'" In re Schlich, 893 F.3d 40, 47 (1st Cir. 2018) (citing Intel Corp., 542 U.S. at 264). The second factor concerns the "receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance." Intel Corp., 542 U.S. at 264. In the third factor, the court considers whether the discovery request "conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States." Id. at 265. "Finally, the fourth factor addresses whether the request is 'unduly intrusive or burdensome' to

the extent that it should either be 'trimmed' or rejected outright." In re Schlich, 893 F.3d at 47 (citing Intel Corp., 542 U.S. at 265).

III. Discussion

A. *Section 1782*

Millennium does not dispute that the mandatory statutory requirements of Section 1782 are met here: Millennium is a resident of this district, the information sought by Petitioners is "for use in a proceeding or international tribunal," the application was made by an "interested person," and the materials sought are not under the protection of a legal privilege. See Opposition 8 n.5 [Doc. No. 31].

B. *Intel Factors*

Millennium objects that the discretionary Intel factors—particularly the fourth factor—are not met here. See Opposition 9-12 [Doc. No. 31].

1. Factor One

The first factor asks the court to consider whether the foreign tribunal has jurisdiction over the party from whom discovery is being sought.

Millennium is not a party to the 2019 EPO invalidity proceedings. Opposition 9 [Doc. No. 31]. Millennium notes that the patentee (the United States of America) submitted Declarations in that proceeding from Alice Choi, the Executive Director of Clinical Operations, and Dr. Paul Richardson, the Principal Investigator on numerous VELCADE studies. Id. at 5; see Choi Decl. [Doc. No. 26]; Decls. of Dr. Paul Richardson ("Richardson Decls.") [Doc. Nos. 26-2, 26-3]. But these submissions do not make Millennium a party such that the EPO has jurisdiction over it.

Millennium brought the German infringement proceeding and has intervened in each of the German nullity proceedings. See Burrichter Decl. ¶¶ 2-4 [Doc. No. 29].

Accordingly, the first factor weighs in favor of granting the discovery request as to the 2019 EPO proceedings and against granting the discovery request as to the German Infringement Proceeding and the German Nullity Proceedings.

2. Factor Two

The second factor asks the court to consider the receptivity of the foreign tribunal to the evidence, including whether "the rules of the foreign tribunal may relegate the information to marginal relevance[,]" such that its introduction would not be beneficial to the foreign proceedings. In re Schlich, 893 F.3d at 52. Millennium contends that neither the German courts nor the EPO would be receptive to the evidence. See Opposition 9-10 [Doc. No. 31].

As to the 2019 EPO Invalidity Proceeding, Millennium cites an EPO rule that the late introduction of evidence requires "exceptional circumstances" to justify admission. Hoggett Decl. ¶¶ 11-12 (citing Article 13(2) of the Rules of Procedure of the Boards of Appeal of the European Patent Office 2020) [Doc. No. 27].[4]

In defense of their delayed request, Petitioners contend that they did not know that their initial evidentiary submission would be insufficient, and that they required additional time to prepare the new discovery request. Pets.' Reply ISO Application ("Reply") 3 [Doc. No. 42]. But a failure to submit all potentially relevant evidence at the outset of a proceeding is unpersuasive as an "exceptional circumstance" justifying additional discovery. Thus, the court agrees with

[4] Consistent with this rule, the EPO rejected a late prior public use challenge in Teva Ltd.'s appeal in the 2016 proceeding. See supra n.2.

Millennium that the second factor weighs against discovery with respect to the 2019 EPO invalidity proceedings.

As to the German infringement proceeding, the German District court's jurisdiction does not extend to rulings on patent validity. And while the court does have the power to stay the infringement proceedings upon a showing of probable success in the nullity proceedings, the court must "base [its] assessment solely on the evidence presented in the respective validity proceeding." Vom Feld Decl. ¶ 8 [Doc. No. 28]. Here, Petitioners acknowledge that the German District court has already postponed the infringement hearing until *after* the German Federal Patent Court nullity proceedings have occurred. Decl. of Dr. Bastian Selck ¶ 13 [Doc. No. 38]. Thus, Petitioners have put forth no independent basis for submitting such evidence to the District court handling the infringement proceedings, particularly where that court's ability to weigh the evidence is severely limited. The court finds for this reason that the second factor weighs against discovery with respect to the German infringement proceeding.

As to the German nullity proceedings, despite the late-breaking nature of Petitioners' request, those proceedings are still open and it does not seem likely that the information, if available, would be excluded on timeliness or admissibility grounds prior to the April 2024 hearing. Cf. Vom Feld Decl. ¶ 12 [Doc. No. 28] (Petitioners are seeking documents that do not run afoul of the German court's rule on impermissible witness testimony). Finally, Millennium's argument that the evidence would be ill-received because of a general prohibition on "fishing expeditions," see id. at ¶¶ 7-10, is better addressed under the fourth factor, infra Section III.B.4. As a result, the second factor weighs in favor of the application as to the German nullity proceedings.

3. Factor Three

The third factor does not require Petitioners to "seek the foreign court's blessing . . . [t]he inquiry here is whether the discovery is being sought in bad faith." Chevron Corp. v. Sheffitz, 754 F. Supp. 2d 254, 262 (D. Mass. 2010). Millennium does not meaningfully dispute that Petitioners have satisfied the third factor and has introduced no evidence suggesting that Petitioners are attempting to undermine or circumvent foreign discovery restrictions in making its request. Thus, the court finds that the third factor weighs in favor of the application as to all of the proceedings.

4. Factor Four

The fourth factor asks the court to consider whether the discovery request is unduly burdensome or intrusive. "[R]equests are unduly burdensome when they are not narrowly tailored, request confidential information, and appear to be a broad 'fishing expedition' for irrelevant information." In re Gen. Elec. Co., 2022 WL 16720425, at *7 (D. Mass. Nov. 2, 2022) (internal quotation marks and citations omitted). Millennium makes two arguments on this point.

First, Millennium takes issue with Petitioners' use of Section 1782 discovery to bolster an expansive theory that Millennium has "already explained in detail . . . is factually baseless." Opposition 11 [Doc. No. 31]. Millennium notes that the prior public use challenge has been raised (and rejected) in numerous proceedings in numerous jurisdictions prior to these hearings, and that two different witnesses have already testified that Millennium did not disclose information about the chemical nature of the lyophilized powder to patients or broader clinical trial staff during the VELCADE clinical trials. Opposition 11 [Doc. No. 31]. The court agrees that Petitioners' continued attempt to seek this information, without any evidence that such

information exists, is the kind of impermissible "fishing expedition" that the Intel factors are designed to protect against.

Second, Millennium argues that even if the evidence were to support Petitioners' point, "[i]t would … be a vast enterprise to search for, locate, and review materials in so far as they can be found for relevance to [the] discovery requests[.]" Id. at 11-12 (citing In re Apotex Inc., 2009 WL 618243, at *4 (S.D.N.Y. Mar. 9, 2009). Millennium estimates that the physical records Petitioners seek—which pertain to over a dozen different clinical trials and are stored offsite—would take hundreds of hours of effort to categorize, redact, and prepare for use in the patent proceedings. Id. at 8, 11. Petitioners respond that they could work with Millennium to "alleviate any undue burden." Reply 4 [Doc. No. 42]. But despite that claim, Petitioners have not narrowed the scope of their discovery request or otherwise indicated how they could or would alleviate the burden on Millennium to produce these documents. Nor have Petitioners addressed evidence already available in the 2016 EPO proceeding where—as here—the challenger was a subsidiary of Teva Ltd. See Opposition 4 [Doc. No. 31], Choi Decl.[5] [Doc. No. 26-1], Richardson Decls.[6] [Doc. Nos. 26-2, 26-3]; cf. In re Gen. Elec. Co., 2022 WL 16720425, at *9 (finding factor weighed in favor of application where company had refuted assumption that evidence was available in the normal course of business from its foreign affiliates).

[5] In her Declaration, Choi provides an informed consent form that does not include any information related to the two patents, and then states that "every patient who participated in the trials [would] have read and then signed such an informed consent form[.]" Choi Decl. ¶¶ 7-8. [Doc. No. 26-1].

[6] Dr. Richardson was the Principal Investigator of several of the potentially relevant clinical trials. In his Declaration, he states that "institution staff were not free to divulge information regarding the identity or nature of the composition [of VELCADE], to the extent that such information was known to them at all." Sec. Decl. of Dr. Richardson ¶ 8 [Doc. No. 26-3].

In sum, the court finds that the fourth factor weighs against granting the application, particularly given the history surrounding Petitioners' (and their affiliates/parent companies') prior attempts to bring this precise public use challenge against Millennium, the absence by Petitioners of any explanation as to how their attempts to obtain the requested documentary material would be more fruitful than previous efforts have been, and the burdensomeness of the inquiry posed by the requested discovery.

IV. Conclusion

Considering only the first three factors, the court would deny the application as to the 2019 EPO proceeding, where the matter is already on appeal and the court unlikely to be receptive to the discovery; would deny the application as to the German infringement proceedings, which is not considering validity; and would find it a close call as to the ongoing German nullity proceedings. Taking into account the fourth factor, however, the court also denies the application as to the ongoing German nullity proceedings, for the reasons set forth above.

For the foregoing reasons, Petitioners' Application [Doc. No. 2] is DENIED.

IT IS SO ORDERED

February 5, 2024

/s/ Indira Talwani

United States District Judge